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December 6, 1999

Document Management Branch
HFA-305
Food & Drug Administration
5630 Fishers Lane
Comment Room 1061
Rockville, MD 20852

Re: Docket #97N-484S

Dear Sirs:

I'd like to offer my comment on the recent proposal, as pubiished in the Federal Register, to regulate allograft bone tissue as a medical device.

This will have a tremendous chilling effect on the quality of patient care in this country. In my practice, we utilize allograft bone to strengthen fusions, and to shorten surgical procedures, as well as providing better outcome. By using allograft bone rather than autograft bone, obtained from the patient himself, we save the patient significant hardship, pain, suffering, and shorten the surgical procedure. The complication rate at bone graft donor sites is not insignificant, and the use of allograft bone completely eliminates this potential complication.

I have been using allograft bone routinely for over 10 years, and have never had a complication related to the allograft bone.

I therefore strongly object to the proposal, as published in the Federal Register on September 30, to allow the FDA to regulate allografl bone as a medical device.

Sincerely yours,

Daniel Spitzer, MD
DS:bs

97N-4845

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* Oiplomate American Board of Neurological Surgeons

Columbia Presbyterian Medical Center Nyack Hospital Good Samaritan Hospital
Horton Hospital Arden Hill Hospital St. Anthony Community Hospital

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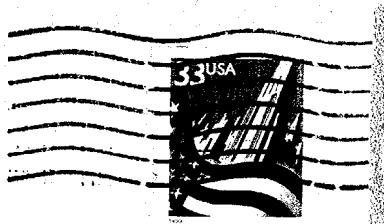

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